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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.     |
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| 10/798,014  | 03/10/2004  | Tae-ahn Jahng        | 001227/1368         | 4949                 |
| 69095   | 7590        | 12/24/2008           | EXAMINER            |                      |
| STROOCK & STROOCK & LAVAN, LLP<br>180 MAIDEN LANE<br>NEW YORK, NY 10038 |             |                      |                     | CUMBERLEDGE, JERRY L |
| ART UNIT  |             | PAPER NUMBER         |                     |                      |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/798,014             | JAHNG, TAE-AHN      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | JERRY CUMBERLEDGE      | 3733                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 September 2008.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,2,4-8,10,15,16,18,22-25,27 and 31-38 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,2,4-8,10,15,16,18,22-25,27 and 31-38 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Claim Objections***

In claim 1 there exists an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear. In the preamble, line 2, applicant recites “A flexible rod” with the first pedicle screw and a second pedicle screw being only functionally recited, i.e. “for mounting between a first pedicle screw and a second pedicle screw...”, thus indicating that the claim is directed to the subcombination, “A flexible rod”. However, in lines 5 and 6, applicant positively recites the pedicle screws as part of the invention, i.e. “ ...a first end received by and coupled to the first pedicle screw; a second end received by and coupled to the second pedicle screw...”, thus indicating that the combination, a flexible rod and pedicle screws, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claim is intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claim 1 will be considered as being drawn to the subcombination, a flexible rod.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Leone (US Pat. 5,488,761).

Leone discloses a flexible connection unit for use in a spinal fixation device comprising a longitudinal rod (Fig. 6) including a first end, a second end, and a longitudinal substantially cylindrical center section (Fig. 6) having a longitudinal axis and an outer surface (Fig. 6), the center section being located between and coupled to the first end and the second end (Fig. 6), the center section including a plurality of grooves (Fig. 6, grooves near ref. 48 and 52) formed in the outer surface of the substantially cylindrical center section (Fig. 6), the plurality of grooves extending circumferentially around the longitudinal axis (Fig. 6) and a plurality of holes (Fig. 6, e.g. near ref. 51, at ends of grooves) formed in the substantially cylindrical center section (Fig. 6), each hole intersecting an end of at least two of the plurality of grooves formed in the outer surface of the rod (Fig. 6). The rod is made from a material selected from the group consisting of stainless steel, iron steel, titanium, titanium alloy and nitinol (column 2, lines 60-64). The grooves are cut toward a center longitudinal axis of the rod (Fig. 6). The rod is solid along a longitudinal section (Fig. 6). The flexible connection unit further includes a plurality of transverse tunnels formed within at least a portion of the solid longitudinal section and wherein each tunnel coincides with at least one hole (Fig. 6, tunnel adjacent hole at end of groove). The rod is solid (Fig. 6) and the first end, the second end and the center section are monolith (Fig. 6) and each transverse tunnel passes through a center longitudinal axis of the cylindrical portion of the rod (Fig. 6). The first end, the second

end and the center are a monolith (Fig. 6). Each of the plurality of grooves is associated with a first hole at a first end and a second hole at a second end (Fig. 6)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leone (US Pat. 5,488,761).

Leone discloses the claimed invention except for the transverse tunnels having an internal diameter between 0.2 and 3 millimeters.

It would have been obvious to a person having ordinary skill in the art at the time the invention was to have constructed each of the transverse tunnels having an internal diameter between 0.2 and 3 millimeters., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 24, 25, 27 and 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (US Pat. 5,573,520) in view of Schwartz et al. (US Pat. 5,573,520).

Schwartz et al. disclose one embodiment comprising a connection unit for use in bony fixation (Fig. 10) comprising a longitudinal metal rod (Fig. 10)(column 7, lines 56-66) having an outer surface including a first end (Fig. 10), a second end (Fig. 10), and a substantially cylindrical center section (Fig. 10) located between and coupled to the first end and the second end (Fig. 10), the center section including a groove formed in the outer surface of the rod (Fig. 10, ref. 52). The rod is made from a material selected from the group consisting of stainless steel, iron steel, titanium, titanium alloy, and NITINOL (column 7, lines 56-66). The grooves are cut toward a center longitudinal axis of the rod (Fig. 10). The first end, the second end, and the center section are a monolith (Fig. 10).

The embodiment of Fig. 10 does not include tunnels; the adjacent tunnels share a common opening on one side of the outer surface of the rod thus forming a zig-zag pattern of tunnels passing transversely through a central longitudinal axis of the rod; the tunnel has a diameter and the grooves have a width, the diameter of the tunnel is at least twice as wide as the width of the grooves; the longitudinal axis of each tunnel being substantially parallel to the longitudinal axis of an adjacent tunnel so that the tunnels are substantially parallel with respect to one another; each tunnel has a longitudinal axis, each tunnel is substantially parallel with respect to one another; and each tunnel is substantially orthogonal to an adjacent tunnel. Each tunnel intersects at least one adjacent tunnel.

Schwartz et al. disclose a second embodiment comprising a plurality of holes through the device (Fig. 9, ref. 52), which form tunnels through the device (by tracing a path from one opening to another opening). Schwartz further discloses that the grooves

formed in the surface of the device can be varied in depth, configuration and spacing in order to adjust longitudinal stiffness and strength of the flexible member (column 8, lines 5-9)(column 9, lines 36-43).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the holes of the embodiment of Fig. 9 of Schwartz with the grooves of the embodiment of Fig. 10 of Schwartz since Schwartz teaches that the grooves can be modified in order to adjust longitudinal stiffness and strength of the flexible member (column 8, lines 5-9)(column 9, lines 36-43). Modifying the reference in this way would produce holes in outer surface of the device 9)(embodiment of Fig. 9) which would form tunnels through the device (by tracing a path from one opening to another opening) and would form holes intersecting a groove (from the hole of embodiment 9 intersecting the groove of embodiment of Fig. 10). The tunnels would form multiple axes, depending which tunnels are traced between which openings (Fig. 9).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed each of the plurality of transverse tunnels having an internal diameter between 0.2 and 3 millimeters., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 15, 16, 18, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US Pat. 5,672,175) in view of Schwartz et al. (US Pat. 5,573,520) and in view of Schwartz (US Pat. 5,573,520).

Martin discloses a flexible connection unit for use in bony fixation (Fig. 1), comprising a first bone coupling assembly (Fig. 1, ref. 7a); and a longitudinal solid metal rod (Fig. 1, 4a, 4b)(column 8, lines 58-66) having an outer surface (Fig. 1), including a first end received by and coupled to the first bone coupling assembly (Fig. 1); a second end (Fig. 1); and a substantially cylindrical center section located between and coupled to the first end and the second end (Fig. 1). The rod is made from a material selected from the group consisting of stainless steel, iron steel, titanium, titanium alloy, and NITINOL (column 8, lines 58-66). The grooves are cut toward a center longitudinal axis of the rod. The first end, the second end, and the center section are a monolith (Fig. 1).

Martin discloses the claimed invention except for the center section including a plurality of grooves formed in the outer surface of the rod, and a plurality of tunnels formed in the center section of the rod, each tunnel including a pair of diametrically opposed openings on the outer surface of the rod, wherein the tunnel openings intersect one of the grooves formed on the outer surface of the rod. Martin does disclose that the longitudinal member is flexible (column 8, lines 58-66).

Schwartz et al. disclose a connection unit for use in bony fixation (Fig. 10) comprising a longitudinal solid metal rod (Fig. 10)(column 7, lines 56-66) comprising a longitudinal solid metal rod (Fig. 10)(column 7, lines 56-66) having an outer surface including a first end (Fig. 10), a second end (Fig. 10), and a substantially cylindrical

center section (Fig. 10) located between and coupled to the first end and the second end (Fig. 10), the center section including a groove formed in the outer surface of the rod (Fig. 10, ref. 52). Schwartz further discloses that the grooves formed in the surface of the device can be varied in depth, configuration and spacing in order to adjust longitudinal stiffness and strength of the flexible member (column 8, lines 5-9)(column 9, lines 36-43).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the flexible longitudinal member of Martin with a groove as taught by Schwartz et al. in order to adjust longitudinal stiffness and strength of the flexible member (column 8, lines 5-9)(column 9, lines 36-43).

Furthermore, Schwartz discloses a second embodiment comprising a plurality of holes through the device (Fig. 9, ref. 52), which form tunnels through the device (by tracing a path from one opening to another opening). Again, Schwartz discloses that the grooves formed in the surface of the device can be varied in depth, configuration and spacing in order to adjust longitudinal stiffness and strength of the flexible member (column 8, lines 5-9)(column 9, lines 36-43).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have further modified the device of Martin with the plurality of holes as taught by Schwartz, in order to adjust longitudinal stiffness and strength of the flexible member (column 8, lines 5-9)(column 9, lines 36-43). Making this second modification of the rod of Martin would produce holes in outer surface of the device (embodiment of Fig. 9) which would form tunnels through the device (by tracing a path

from one opening to another opening) and would form holes intersecting a groove (from the hole of embodiment 9 intersecting the groove of embodiment of Fig. 10).

***Response to Arguments***

Applicant's arguments filed 09/23/2008 have been fully considered but they are not persuasive.

With regard to Applicant's arguments directed to the pedicle screws and their associated functionality, the examiner notes that for examination purposes claim 1 will be considered as being drawn to the subcombination, a flexible rod, as it is ambiguous as to whether the combination or subcombination is being claimed.

With regard to Applicant's arguments directed to the intersection of the holes, upon further consideration, the examiner notes that combining the embodiments as described above will produce intersecting grooves and holes as the groove of the embodiment of Fig. 10 is continuous and would necessarily intersect the openings of the embodiment of Fig. 9 as the groove traverses the length of the rod.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./  
Examiner, Art Unit 3733

/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733